

Notice of Allowability

Application No.

09/559,799

Examiner

Sharmila S. Gollamudi

Applicant(s)

PIAO ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/31/03.
2. ☒ The allowed claim(s) is/are 1 and 3-13.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

THURMAN K. PAGE
SUPERVISORY/PATENT EXAMINER
TECHNOLOGY CENTER 1600

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Cheng on January 13, 2004.

The application has been amended as follows:

In claim 1, line 11, after "polymer blocks" add "and wherein an aqueous solution of said Component I triblock copolymer has a lower gelation temperature than an aqueous solution of said Component II triblock copolymer".

Cancel claims 14-36.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The closest prior art, US 6,004,573, neither discloses nor fairly suggests a mixture of *different* triblock copolymers with instant properties. Further, US 5,702,717 neither discloses nor fairly suggests a high content of hydrophobic block copolymers wherein the polymeric system is water-soluble. The instant invention is a specific combination of triblock copolymers with each component having a specific molecular weight to impart an improved drug delivery and reverse gelation properties. The specific combination provides for a high content of hydrophobic copolymers with the result of maintaining a polymeric system that is water-soluble.

Although, US patents 6,287,588 and 6,589,549 having the same assignee and are directed toward block polymers, the US patents are not directed to a specific mixture of two tri-block copolymers as seen in instant applicant and thus are not obvious modifications over each other. Although, claim 7 of '588 and '549 briefly recite a mixture of two or more block polymers, the US patents do not recite a mixture of triblock polymers with specific molecular weights or gelation temperatures. Further, although claim 8 of US patent '588 and '549 recite triblock copolymers, this claim does not depend on 7. Thus, there is no limitation of having a mixture of two triblock polymers with specific molecular weights. Secondly, US patents claim formulation with different phases, i.e. a continuous phases and a discontinuous phase, whereas the instant application only has a continuous phases.

Therefore, there is no motivation to arrive at the instant mixture of instant triblock polymers with instant molecular weight. Further, there is no motivation to modify the US patents and change the gelation temperature of each triblock component such that component I triblock has a lower gelation temperature than component II. This gelation temperature and molecular weight affords a better drug release.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-

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272-0614. The examiner can normally be reached on M-F (8:00-5:00) with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

June 7, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 4600